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### 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

**Submitter's Name:** Guidant Corporation  
Advanced Cardiovascular Systems, Inc.

**Submitter's Address:** 3200 Lakeside Drive  
Santa Clara, CA 95052

**Telephone:** 408/845-1067  
**Fax:** 408/845-3743

**Contact Person:** Saba Modjarrad

**Date Prepared:** June 15, 2001

**Device Trade Name:** DYNALINK™ .035 Biliary Self-Expanding Stent System

**Device Common Name:** Biliary Stent

**Device Classification Name:** Biliary Catheter

**Device Classification:** Class II

#### Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of DYNALINK™ .035 Biliary Self-Expanding Stent System with stents in diameters of 5-10 mm and lengths of 28, 38, and 56 mm are substantially equivalent with regard to these features in the predicate device, the DYNALINK™ Biliary Self-Expanding Stent System (K002143, October 12, 2000).

#### Device Description:

The DYNALINK™ .035 Biliary Self-Expanding Stent System is a catheter designed to deploy a self-expanding nickel titanium (Nitinol) stent into the biliary tree.

The catheter body is constructed from two coaxial members. The inner member (IM) is compatible with a 0.035" guide wire in an over-the-wire configuration. The outer member (OM) is composed of a distal sheath that constrains the unexpanded stent, an outer shaft over most of the catheter length, and a proximal handle used to retract the assembly.

The distal end of the delivery system includes the DYNALINK™ Biliary Self-Expanding Stent held in its constrained state by the stent-restraining sheath, a soft, low profile tip, and two radio-opaque markers to indicate the proximal and distal ends of the stent. At the proximal end of the delivery system, the user interface is composed of a pull-back handle attached to the OM, a shaped housing that allows the handle to slide axially, and a luer fitting that is rigidly fixed to the shaped housing.

The DYNALINK™ Biliary Self-Expanding Stent is fabricated from superelastic nickel-titanium (nitinol). The DYNALINK™ Biliary Self-Expanding Stent is comprised of a series of serpentine rings that are aligned along a common longitudinal axis.

The stent is laser cut from a tube of superelastic nitinol. All of the stent diameters are cut with similar stent patterns, and the stent is expanded and heat-treated to be stable at the desired final diameter. The stents are electropolished to obtain a smooth finish with a thin layer of titanium oxide on the surface.

The DYNALINK™ Biliary Self-Expanding Stent is available in diameters of 5-10 mm and in lengths of 28, 38, and 56 mm.

**Intended Use:**

The DYNALINK™ .035 Biliary Self-Expanding Stent System is indicated for palliation of malignant strictures in the biliary tree.

**Technological Characteristics:**

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices. The design modification of the new biliary stent system compared to that of the predicate biliary stent system is the length of the stent.

**Performance Data:**

The safety and effectiveness of the DYNALINK™ .035 Biliary Self-Expanding Stent System has been demonstrated through data collected from *in vitro* bench tests and analyses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 1 8 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Saba Modjarrad  
Regulatory Affairs Coordinator  
Guidant Corporation  
Vascular Intervention Group  
3200 Lakeside Drive  
Santa Clara, California 95054

Re: K011881  
DYNALINK™ .035 Biliary Self-Expanding Stent System  
Regulatory Class: II  
21 CFR §876.5010  
Product Code: 78 FGE  
Dated: June 15, 2001  
Received: June 18, 2001

Dear Ms. Modjarrad:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

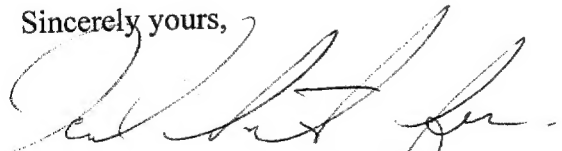
Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

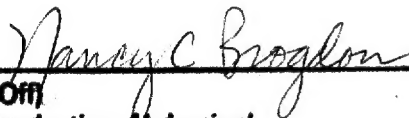
Enclosure

510(k) Number (if known): K011881

Device Name: DYNALINK™ .035 Biliary Self-Expanding Stent System

FDA's Statement of the Indications For Use for device:

The DYNALINK™ .035 Biliary Self-Expanding Stent System is indicated for the palliation of malignant strictures in the biliary tree.

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K011881

Prescription Use 1 OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)